APHIS Factsheet

Animal and Plant Health Inspection Service May 2005

Questions and Answers on the Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Select Agents and Toxins

Q. What is the Agricultural Bioterrorism Protection Act of 2002?
A. This law is a subpart of the Public Health Security and Bioterrorism Preparedness Response Act of 2002, which was signed into law by the President on June 12, 2002. Both require that entities, such as private, State, and Federal research laboratories; universities; and vaccine companies that possess, use, or transfer agents or toxins deemed a threat to public health and safety or to animal or plant health or products register these agents with the appropriate Federal Department.

Q. Under these acts, what Departments are responsible for regulating the possession of these agents and toxins?
A. Under the Agricultural Bioterrorism Protection Act, entities that possess, use, or transfer agents or toxins deemed a severe threat to animal or plant health or products must notify and register with the Secretary of the U.S. Department of Agriculture (USDA). USDA's Animal and Plant Health Inspection Service (APHIS) has been designated by the Secretary as the agency responsible for implementing the provisions of the law for USDA.

Under the Public Health Security and Bioterrorism Preparedness Response Act, entities that possess, use, or transfer toxins or agents deemed a threat to public health must register with the Secretary of the U.S. Department of Health and Human Services (HHS). The Centers for Disease Control and Prevention (CDC) has been designated by the HHS Secretary as the agency responsible for implementing the provisions of the law for HHS.

Q. Why was the Public Health Security and Bioterrorism Preparedness Response Act enacted?
A. This law is designed to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies that could threaten public health and safety or American agriculture.

Q. What agents or toxins pose a severe threat to public health, animal or plant health, or products?
A. The list of select agents and toxins deemed to pose a severe threat to animal or plant health or products was published in the March 18, 2005, *Federal Register,* under Title 7 CFR, Part 331 and Title 9 CFR, Part 121. To see the text, go to <http://www.aphis.usda.gov/programs/ag_selectagent/index.html>. These agents and toxins fall under the responsibility of USDA.

The list of select agents and toxins deemed to pose a severe threat to public health was published in the March 18, 2005, *Federal Register* under Title 42 Code of Federal Regulations (CFR), Parts 72 and 73. To see the text, go to http://www.cdc.gov/od/sap on the Web. These agents and toxins fall under the responsibility of HHS.

Q. What were the criteria used to determine whether an agent or toxin should be on the USDA list?
A. In determining whether an agent or toxin should be included on the USDA list, the criteria considered include, but are not limited to:

- The effect of an agent or toxin on animal or plant health or products.
- The virulence of an agent or degree of toxicity of the toxin and the methods by which the agents or toxins are transferred to animals or plants.
- The availability and effectiveness of medicines and vaccines to treat and prevent any illness caused by an agent or toxin.

In addition, several provisions are included based on the individual needs of VS and the individual needs of PPQ.

Q. What are "overlap agents"?
A. Some of the agents and toxins that pose a severe threat to animal health and animal products also pose a severe threat to public health and safety. As such, these agents and toxins also appear on both the HHS and the USDA's lists of agents and toxins and have been designated "overlap select agents and toxins" because both USDA and HHS have regulatory authority over them.

Q. Who is affected by the regulations?
A. Everyone possessing, using, or transferring **any** select agent or toxin is affected by the regulations. Some examples include private, State, and Federal research laboratories; universities; vaccine companies; and individuals.

Q. How do entities become registered?
A. Registration of an entity requires that an "Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins" be completed and submitted to either CDC or APHIS. Registration also requires that the U.S. Department of Justice complete a security risk assessment for the facility, its owners, the designated responsible official, and all individuals possessing, using, or transferring the agents or toxins. Before registration is granted, the facility must also meet biosafety requirements that are commensurate with the risk that the agent or toxin poses and must establish security measures that provide graded protection in accordance with the threat that the agent or toxin poses.

An entity that needs to register in order to possess, use, or transfer an overlap select agent or toxin must submit its registration information to either APHIS or CDC but is not required to submit the application to both APHIS and CDC.

Q. Will my entity require an inspection?
A. Yes, registration requires an inspection. Additionally, without prior notification, program inspectors are allowed to inspect any site at which activities regulated by this part are conducted and are allowed to inspect and copy records relating to activities covered by Title 7 CFR, Part 331 and/or Title 9 CFR, Part 121.

Q. Are permits also required?
A. Yes. APHIS' Veterinary Services (VS) program regulates overlap select agents and toxins and animal–specific agents and toxins as "organisms and vectors" under Title 9 CFR, Part 122, just as APHIS' Plant Protection and Quarantine (PPQ) program regulates plant–specific agents as plant pathogens under Title 7 CFR, Part 330. These regulations prohibit the importation into the United States or interstate movement within the United States of organisms, vectors, and plant pathogens unless an appropriate permit has been issued by APHIS. Prior to the movement of animal–specific select agents and toxins, a VS Form 16–3 is required. The movement of plant–specific select agents requires a PPQ Form 526. Please contact the VS permit unit at (301) 734–5960 or the PPQ permit unit at (301) 734–5519 for further information.

Q. Are there any exemptions to the new registration requirements?
A. Entities such as pharmacies, clinics, and hospitals that exclusively possess products that contain any of these agents or toxins and that are cleared, approved, licensed, or registered under any of the acts listed below are exempt from the registration requirement:

- Federal Food, Drug, and Cosmetic Act;
- Section 351 of the Public Health Service Act;
- Virus–Serum–Toxin Act; and the
- Federal Insecticide, Fungicide, and Rodenticide Act.

APHIS will determine on a case–by–case basis whether certain investigational products that contain select agents pose no threat to animal health or animal products and may be exempted.

Additionally, diagnostic facilities for either animal or plant diseases are exempt if they report the identification of any select agent or toxin and either destroy or transfer the agent or toxin within seven days, according to the regulations.

Q. What is the penalty for noncompliance under the regulations?
A. Entities found to possess, use, or transfer select agents or toxins that are not registered with either CDC or APHIS are subject to a fine of $500,000 for the entity and $250,000 and/or imprisonment for up to 5 years for an individual. These penalties also apply to an entity or individual transferring any of these agents or toxins to a nonregistered entity.

Q. How is the owner of an entity defined?
A. In a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual owns 50 percent or more of its voting stock or is in a managerial or executive capacity with regard to select agents or toxins possessed, used, or transferred by the entity.

Q. What is required of diagnostic labs?
A. Both registered and exempt entities must report the identification of a select agent or toxin that is contained in a specimen presented for diagnosis, verification, or proficiency testing. Upon identification, an exempt entity must secure the agent or toxin against theft, loss, or release until the transfer or destruction of the agent or toxin. During the period between identification of a select agent or toxin and its transfer or destruction, an exempt entity must

report any theft, loss, or release of the agent or toxin. Registered entities are also required to secure a select agent or toxin and report its theft, loss, or release.

Clinical and diagnostic facilities that do not maintain viable agents or active toxins are exempt from the registration requirements, provided that they notify APHIS of the identification of the agent or toxin and then either destroy or transfer it to a registered entity within 7 days of identification. For overlap agents, a clinical or diagnostic facility must notify either APHIS or CDC.

Q. What are the notification requirements?
A. The identification of any of the following select agents or toxins must be *immediately* reported by telephone, facsimile, or e–mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), *Bacillus anthracis, Botulinum* neurotoxins, bovine spongiform encephalopathy agent, *Brucella melitensis,* classical swine fever virus, foot–and–mouth disease virus, *Francisella tularensis, Hendra* virus, *Liberobacter africanus, Liberobacter asiaticus,* Newcastle disease virus (velogenic), Nipah virus, *Peronosclerospora philippinesis, Ralstonia solanacearum* race 3 biovar 2, Rift Valley fever virus, rinderpest virus, *Sclerophthora rayssiae* var. *zeae,* swine vesicular disease virus, *Synchytrium endobioticum,* Venezuelan equine encephalitis virus, *Xanthomonas oryzae* pv. *oryzicola,* and *Xylella fastidiosa* (citrus variegated chlorosis strain). The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

Q. What does the term "access" mean?
A. The regulations state that "an individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin."

Q. Is genetic material regulated?
A. Nucleic acids that can produce infectious forms of any of the select agent viruses (e.g., foot–and–mouth disease, classical swine fever, Japanese encephalitis virus, swine vesicular disease virus, genomes of positive strand RNA viruses on the select agent lists such as eastern equine encephalitis virus, Venezuelan equine encephalitis virus, and tick–borne encephalitis complex [flavi] viruses) are regulated and must be registered.

Q. Will my current certificate of registration remain valid once the final rule takes effect?
A. Yes. All registration certificates issued under the amended interim final rule will remain valid until the expiration date provided on the entity's certificate of registration or until that certificate is revoked. The same criteria apply to security risk assessments.

Entities currently registered are not required to submit a new application when the final rule becomes effective. However, the responsible official should review all sections under the final rule to determine if any of the changes throughout the regulation dictate a modification to the information submitted to the USDA Secretary. The responsible official should immediately apply for an amendment to a certificate of registration by submitting the relevant page(s) of the application to the USDA Secretary.

Q. Where can applicants get the forms associated with the Agricultural Bioterrorism Protection Act of 2002?
A. A single form number will be used for each of the identical forms used by USDA and HHS. For example, the "Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins" is APHIS/CDC Form 1.

Copies of the forms may be printed from the APHIS Web site at http://www.aphis.usda.gov/programs/ag_selectagent/index.html or from the CDC Web site at <http://www.cdc.gov/od/sap>. APHIS and CDC have developed joint reporting systems so that the same forms may be used for either agency.

Q. Where should registration applications be sent?
A. To submit documents to USDA–APHIS, please mail them to:

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road, Unit 2, Mailstop 22,
Cubicle 1A07
Riverdale, MD 20737–1231

To submit documents to CDC, please mail them to:
Centers for Disease Control and Prevention
1600 Clifton Road NE, MSE–79
Atlanta, GA 30333

Q. Where can applicants get additional information?

A. For more information on select agents and toxins, please visit either the APHIS Web site at http://www.aphis.usda.gov/programs/ag_selectagent/index.html or the CDC Web site at <http://www.cdc.gov/od/sap>. Applicants may also call APHIS directly at (301) 734–5960 or e–mail agency personnel at <agricultural.select.agent.program@aphis.usda.gov>. To reach the CDC, please call (404) 498–2255 or e-mail <lrsat@cdc.gov>.
